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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jill Embry

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EXAMINER

KINNAL, ELIZABETH ANN

ART UNIT

PAPER NUMBER

4158

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/812,582	Applicant(s) EMBRY ET AL.	
	Examiner Elizabeth A. Kinnal	Art Unit 4158	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/30/2004, 11/01/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-2, 5-8, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Evans et al. (US PG Pub 2004/0204715 A1).

3. Regarding claims 1-2, '715 discloses a delivery system made up of a housing (200) which is divided into a handle (220) and a coupling member (210). '715 also discloses a plunger member (100) made up of a threaded section (114) and a knob (120). Further, '715 discloses a reservoir (300)

4. In regards to claims 5-7, the threaded portion (114) of '715 is adapted to engage with the coupling portion (Pg 3, Para 43). '715 discloses tubing (310) and an orifice (Pg 3, Para 46) through the distal end of the reservoir (300).

5. In regards to claims 8-9, '715 discloses a handle (220) which undulates to provide a better fit in the user's hand.

6. Regarding claims 11, '715 discloses a threaded flange to engage with the threaded portion of the reservoir (Pg. 3, Para 47).

7. Claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by Solomon (USPN 5,842,786).

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8. Regarding claim 27, '786 discloses a device for storing a viscous fluid (10) to be later ejected. Additionally the device of '786 has a mixer (31) to mix the fluid, the mixer being disposed inside the plunger and the plunger being disposed in the storage reservoir.

9. Claims 30-32, are rejected under 35 U.S.C. 102(e) as being anticipated by Evans et al. ('715)

10. The device of '715 provides a system with a housing, plunger member, and reservoir member all coupled by threading. '715 also discloses a method of loading the fluid, engaging the reservoir member, engaging the plunger member, and actuating the plunger member (Claim 28).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. ('715) as applied to claims 1-2 above in view of Sand et al. (USPN 6,645,213). '715 substantially discloses all of the claimed limitations as set forth above. Additionally '715

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discloses a structure to allow the plunger member to effectively expel the fluid from the reservoir, but does not disclose a plunger head attached to the plunger member. '213 discloses a plunger head (308) with a flared shape equal in size to the inner annular surface of the reservoir to provide a seal against in the interior wall of the reservoir. It would have been obvious to one of ordinary skill in the art at the time of the invention to improve the sealing structure of '715 with the plunger head of '213 to provide an improved seal between the plunger member and the wall of the reservoir.

14. Claims 3-4, and 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. '715 as applied to claims 1-2, and 9 above, and further in view of Condon (USPN 5,307,841). '715 substantially discloses all of the claimed limitations as set forth above. Additionally '715 discloses a knob at the proximal end of the disclosed device. However the knob of '715 is flat. '841 discloses a knob (18) which is hemispherical in shape with an undulating cross section, the hemispherical portion being a uniform compression surface. At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the knob of '715 with the knob of '841 to allow the user to push the knob while simultaneously rotating the knob.

15. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. '715. '715 discloses a handle extending from the coupling portion formed to fit the user's hand. Applicant has recited the claimed obtuse angle as a preferred embodiment, and has failed to establish any criticality with respect to the specified angle range. Absent criticality or unexpected results, one of ordinary skill in the art at the time of invention would have been inclined to select various angle sizes for the angle between the handle and coupling portion including the claimed range.

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16. Claims 14-15, 17-21, and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solomon ('786) in view of Sand et al. ('213).

17. Regarding claims 14-15, 17, 20-21, and 23-25, '786 discloses a reservoir (16) with an orifice (21) located at the distal end. A plunger member (30), which is generally T-like in shape is coupled to the reservoir and contains a bore through which a mixing member (31) is disposed. The coupling of the mixing member to the plunger member and the plunger member to the reservoir is not disclosed to be threaded. However '213 discloses a coupling between components to be threaded for better user control of the movement of the separate components (Col 14, Lines 58-63). It would have been obvious to one of ordinary skill in the art at the time of the invention to improve the coupling of the '786 device with the threading type coupling of the '213 device.

18. Regarding claims 18-19 and 21, '786 discloses a mixing member made by attaching a mixer (44) with a plurality of blades (46) to a mixer handle (60). The mixer entering the plunger member from one end and the handle from the other end to connect within the plunger member.

19. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solomon ('786) as applied to claims 14-15 above, and further in view of Solomon (USPN 4,277,184). '786 substantially discloses all of the claimed limitations as set forth above. '786 does not disclose a funnel for aiding in the loading of the reservoir. '184 discloses a funnel (18) to be placed in the proximal end of the reservoir to provide easier loading of the reservoir. Both the device of '786 and the device of '184 are used for mixing a viscous material before delivering it from the reservoir in which it was mixed. It would have been obvious to one of ordinary skill in the art at the time of the invention to add the funnel of the '184 device to the device of '786.

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20. Claims 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solomon ('786) as applied to claims 14, 18, and 21 above, and further in view of Brown et al. (USPN 6,592,247). '786 substantially discloses all of the claimed limitations as set forth above. The blades of '786 however, do not contain slots. '247 discloses a set of blades with holes to reduce the amount of material needed to form the blades and to ensure thorough mixing (Col 6, lines 18-24). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the blades of '786 with the blades of '247 to improve functionality of the blades.

21. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solomon ('786) in view of Sand et al. ('213) as applied to claim 14 above, and further in view of Chen (US PG Pub 2005/0148945 A1).

22. '786 in view of '213 substantially discloses all the claimed limitations as set forth above. The device of '213 discloses a housing on the syringe for holding the device while applying force to the knob at the proximal end of the device (Col 14, lines 28-31). However this housing is not shaped to fit the user's hand. '945 discloses a syringe grip undulated to provide a better manual grip (Pg. 1, Para 17). It would have been obvious to one of ordinary skill in the art at the time of the invention to improve the grip of '213 with the grip of '945.

23. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. ('715) in view of Condon ('841).

24. '715 discloses a device made up of a housing (200) which is divided into a handle (220) and a coupling member (210). '715 also discloses a plunger member (100) made up of a threaded section (114) and a knob (120). Further, '715 discloses a reservoir (300). The threaded portion (114) of '715 is adapted to engage with the coupling portion (Pg 3, Para 43). '715 discloses

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tubing (310) and an orifice (Pg 3, Para 46) through the distal end of the reservoir (300).

Additionally, '715 discloses a threaded flange to engage with the threaded portion of the reservoir (Pg. 3, Para 47). Evans et al. substantially discloses all of the claimed limitations as set forth above. Additionally Evans et al. discloses a knob at the proximal end of the disclosed device. However the knob of Evans et al. is flat. '841 discloses a knob (18) which is hemispherical in shape with an undulating cross section, the hemispherical portion being a uniform compression surface. At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the knob of '715 with the knob of '841 to allow the user to push the knob while simultaneously rotating the knob.

25. Claims 33 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. ('715). The method of '715 discloses actuating the knob with a rotational force. Though '715 does not disclose a compression force, the plunger member advances to eject the viscous fluid and would require compressive force to advance such a fluid. It would have been obvious to one of ordinary skill in the art that applying a rotational force would also apply a compressive force to the knob.

26. Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solomon ('786) in view of Sand et al. ('213).

27. Regarding claims 34-36 '786 discloses a method of providing a plunger member, a mixer assembly, inserting a plunger member, a mixer and mixer handle through a bore in the plunger member. (Claim 7) '786 does not disclose combining the components with the respective threading and does not disclose actuation of the device with compressive or rotational forces. However, the device of '213 has components that are engaged through threading and would

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require compressive and rotational forces to actuate. It would have been obvious to one of ordinary skill in the art at the time of the invention that in using the device of '786 modified by '213, the method would occur.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth A. Kinnal whose telephone number is (571)270-7037. The examiner can normally be reached on Monday through Friday 8:30 am to 6:30 pm, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth A. Kinnal/
Examiner, Art Unit 4158
11/5/08

/Gary Jackson/
Supervisory Patent Examiner
Art Unit 4158